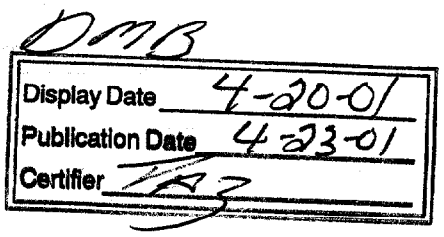
DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

21 CFR Part 660

[Docket No. 00N–1586]

Revision to Requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of June 11, 2001, for the direct final rule that appeared in the **Federal Register** of December 12, 2000 (65 FR 77497). The direct final rule rule amends the biologics regulations applicable to microbiological controls for licensed Anti-Human Globulin and Blood Grouping Reagents by removing the requirement that these products be sterile. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: June 11, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 12, 2000 (65 FR 77497), FDA solicited comments concerning the direct final rule for a 75-day period ending February 26, 2001. FDA stated that the effective date of the direct final rule would be on June 11, 2001, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby will go into effect on June 11, 2001.

Dated: 4/13/01

April 13, 2001.

William Hubbard

William K. Hubbard,
Senior Associate Commissioner
for Policy, Planning, and Legislation.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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